

## **Remarks**

This submission is made in response to the Office Action dated February 20, 2009.

## **Status of the Claims**

Claim 1 has been amended to include the limitations of former claims 2, 3, and 11, which have been cancelled. Claim 16 has been cancelled. New claims 23-30 have been added, the subject matter being supported by the description as originally filed (see, for example, paragraphs [0009], [0031] and [0054]). Claims 1, 4-10, 12-15, and 17-30 are currently pending.

## **Rejections under 35 USC 102**

With regard to the rejections under 35 USC 102(b), it is respectfully submitted that the rejections are moot in view of the claim amendments which distinguish between the cited art and the claimed subject matter.

**Ottersbach (CA 2,384,427)**. The Examiner rejected claims 1-5 and 11-21, saying that they are disclosed by Ottersbach. It is respectfully submitted that Ottersbach does not teach amphiphilic copolymers having "one or more discrete hydrophobic segments and one or more discrete hydrophilic segments containing cationic functionality..." as presently claimed.

Ottersbach teaches copolymers, obtainable by copolymerizing an acryloyl aminoalkyl monomer (see formula III, page 5) with 5-98 mol% of at least one other aliphatically unsaturated monomer. However, Applicant submits that the resulting copolymer does not have discrete hydrophobic and hydrophilic segments, as defined in claim 1 of the present application. In Examples 1, 2, 3, 4, 7, 8, 9 and 10, Ottersbach teaches that the hydrophilic and hydrophobic monomers are charged to a flask and polymerized, allowing the polymerization reaction to proceed for 72 hours. Examples 5, 6 teaches polymerization of the monomer mixture for 15 minutes in an irradiation chamber. It would, therefore, be clear to a skilled reader that the hydrophilic component of the polymer, (i.e. the acryloyl aminoalkyl moiety) is dispersed randomly throughout the polymer and is not present in any discrete blocks. The hydrophobic moiety, (e.g. the aliphatically unsaturated moiety), is also dispersed randomly throughout the polymer and is not present in any discrete blocks. In summary, Applicant

submits that the polymers taught by Ottersbach cannot be said to contain discrete hydrophobic and hydrophilic segments.

In contrast, Applicant submits that the present application defines polymers having discrete hydrophobic and hydrophilic segments. Figures 1 and 2 of the application clearly show examples of various polymers contemplated by the inventors, the contemplated polymers each having discrete hydrophobic segments separate from discrete hydrophilic segments containing cationic functionality. To illustrate, Example 1 shown on page 7 of the present application shows AMA copolymerized with PPO-Me. The PPO-Me has a long hydrophobic oligomeric block, resulting a copolymer with a cationic backbone (the cationic charge coming from the AMA) and the oligomeric blocks extending from the backbone, as illustrated in Figure 2.

The polymers of the present application are therefore, by definition, amphiphilic (combining hydrophilic and hydrophobic segments) as they contain hydrophilic segments with cationic functionality. Their amphiphilicity is demonstrated by their inverse temperature solubility in water (Table 2 of PCT Specification), which only occurs for amphiphilic molecules.

Additionally, Applicant submits that the polymers taught by the cited references do not teach *selective* antibacterial activity, which is conferred by the composition and spatial arrangement of discrete hydrophobic and hydrophilic segments containing cationic functionality. The types of polymers disclosed in the cited reference have been extensively researched and reported to exhibit varying degrees of antibacterial activity. In fact, they not only kill bacteria but also mammalian cells. Due to their toxicity to human cells, they have been employed mostly as disinfectants or biocidal coatings to prevent bacterial accumulation on articles that are not typically in prolonged contact with the body. This is evidenced by the description of the cited references, which predominantly discloses contemplated uses in articles *outside* of the body. (See, for example: page 11 lines 4-18 of corresponding CA application (CA 2,384,427)).

Since Ottersbach does not teach or suggest the claimed subject matter, it is respectfully requested that the Examiner withdraw the rejection under 35 USC 102(b) based on Ottersbach.

**Oster** (US 5,019,496). The Examiner rejected claims 1-6, 9, 13-15 and 18-19 as being anticipated by Oster. Oster teaches a diagnostic test composition for detecting and measuring an analyte possessing biological activity, comprising a photocatalyst system, containing the analyte of interest, capable of converting a monomer to a polymer upon exposure to light and at least one monomer capable of undergoing addition polymerization. The basic principle being that when the analyte, or analyte linked to a photosensitizer, and the monomer mixture are exposed to light, the monomers react to form a polymer that may be characterized. The polymerization reaction amplifies the initial analyte signal, making detection of very low concentrations possible.

Oster teaches that one or more monomers can be used singularly or in combination to amplify the signal, and lists various contemplated monomers in column 11, lines 31-45 and in claim 1. However, Oster does not teach that one hydrophobic monomer and one hydrophilic monomer having cationic functionality should be chosen from the list.

Further, even if a hydrophilic and a hydrophobic monomer were randomly selected, a skilled person would appreciate that copolymerizing a mixture of two monomers would disperse the monomers randomly throughout the copolymer. Therefore, Oster does not teach the formation of discrete hydrophobic and hydrophilic segments.

Applicant submits that the present application defines polymers having discrete hydrophobic and hydrophilic segments. Figures 1 and 2 of the application clearly show examples of various polymers contemplated by the inventors, the contemplated polymers each having discrete hydrophobic segments separate from discrete hydrophilic segments containing cationic functionality. To illustrate, Example 1 shown on page 7 of the present application shows AMA copolymerized with PPO-Me. The PPO-Me has a long hydrophobic oligomeric block (e.g.  $n \approx 5$ ), resulting a copolymer with a cationic backbone (the cationic charge coming from the AMA) and the oligomeric blocks extending from the backbone, as illustrated in Figure 2.

The polymers of the present application are therefore, by definition, amphiphilic (combining hydrophilic and hydrophobic segments) as they contain hydrophilic segments with cationic functionality. Their amphiphilicity is demonstrated by their inverse temperature solubility in water (Table 2 of PCT Specification), which only occurs for amphiphilic molecules.

Furthermore, the Examiner states that Oster describes the use of PPO-Me (which Applicant describes as an A block). In fact, Oster et al claim the use of propylene glycol methacrylate, NOT polypropylene oxide monomethacrylate. The essential difference is that propylene glycol methacrylate contains only 1 propylene glycol unit connected to the methacrylate polymerizable group. PPO-Me contains a polymerized block of propylene glycol repeat units connected to the methacrylate polymerizable group. Since it is well known that polymers physical and chemical properties differ markedly from their parent monomers, it follows that these two monomers will differ markedly as well.

Since Oster does not teach or suggest the claimed subject matter, the Applicant respectfully requests that the Examiner withdraw the rejection under 35 USC 102(b) based on Oster.

**Texter** (US 5,288,745). The Examiner rejected claims 1-6, 9-10 and 20 as being anticipated by Texter, saying that Texter teaches barrier layers comprised of copolymers of formula A-B, the preferred A polymers including AMA, BMA, and MMA. According to the Examiner, the barrier copolymer could be block copolymers chosen from polymethylene oxide, PPO, and polyurethanes, substituted with methacrylate end groups (abstract, claims, and col. 15, line 12 – col 17 line 68).

Applicant submits that the current claim 1 is limited to polymers having a grafted chain architecture, comprising a main chain and chains grafted onto the main chain. Texter teaches both random linear and block linear copolymers, but does not teach grafted chain architecture. Grafted chain architecture provides a different chain architecture than the linear copolymers described by Texter. It is well known in the art that linear and grafted polymers have different properties, and in this case said graft architecture would affect the interaction of the copolymer with the bacterial cell wall. Furthermore, the Applicant has shown that such graft copolymers have selective antimicrobial activity.

Since Texter does not teach grafted chain architecture, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 USC 102(b).

The Examiner's rejection of claim 20 is not understood. It appears that Texter does not disclose an apparatus comprising the copolymer of the invention.

### **Rejection under 35 USC 103**

**Texter** (US 5,288,745). The Examiner rejected claims 1-10, 20 and 22 as being obvious in view of Texter. The Examiner says that, while Texter does not disclose the specific amounts of monomers recited within claims 7, 8 and 22, it would be an obvious, routine practice to optimize the monomers taught in order to reach the desired effect.

Texter teaches, as the Examiner notes, how to change the dissolution properties of the taught polymer. At no point does Texter teach that the polymers have antimicrobial properties. Thus, the desired effect taught by Texter is totally different than the desired effect taught by the present invention. Therefore, it is respectfully submitted that such "optimization" is neither suggested by Texter, nor could it be said to be routine, since the purposes of the two inventions are very different.

Furthermore, as already discussed above, the ancient defense polymer claims have been limited to polymers having a graft chain architecture. Texter does not teach or suggest such graft chain architectures, and, in fact, it is unlikely that such grafted polymers would be useful in the barrier polymer of his diffusion transfer process.

Given the different purpose of Texter, and the lack of any teaching of graft chain architecture polymers, it is respectfully submitted that the present claims are non-obvious in view of Texter, and the Examiner is asked to withdraw the objection.

## **Conclusion**

In summary, the Applicant respectfully requests that the Examiner withdraw the rejections raised under 35 USC 102 and 35 USC 103, as the cited references do not teach or suggest the claimed subject matter.

The Commissioner is hereby authorized to charge any additional fees, and credit any over payments, to Deposit Account No. 501593, in the name of Borden Ladner Gervais LLP.

Respectfully submitted,

**MAY, Michael, H. et al.**

By: /Gail C. Silver/

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